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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,290

05/09/2005

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EXAMINER

RAE, CHARLESWORTH E

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

05/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,290

Applicant(s)

TAKASU ET AL.

Examiner

Charleswort Rae

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1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/9/05; 4/13/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION***Status of Claims***

Claims 1-10 are pending in this application and are the subject of the Office action.

Nonstatutory Obviousness-Type Double-Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 6-12 of U.S. Patent 6,346,532 ('532). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims. The terms optical isomer, hydrate, solvate, and polymorphic substance as recited in reference claims 9 and 10, are reasonably construed to be obvious variants of (R)-2-(2-aminothiazol-4-yl)-4'[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide in the absence of evidence to the contrary. In particular, claim 6 of reference '532 is drawn in part to the instant claimed compound:

(R)-2-(2-aminothiazol-4-yl)-4'[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide.

With respect to the instant claims, no patentable weight is being given to the "intended use" (i.e. overactive bladder, urinary incontinence, urinary urgency, and pollakiuria) of the instant claims as these claims are construed as directed to a composition. Thus, someone of skill in the art at the time the instant invention would have deemed it obvious to create the instant invention with a reasonable expectation of

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success in view of was created o the extent that claimed subject matter overlaps with reference claim 6, the instant claims are deemed to be anticipated by Reference '532.

This is an obviousness-type double patenting rejection because the conflicting claims of '532 have been patented.

Claims 1-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending U.S. Patent Application No. 10/494018. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are either anticipated by, or would have been obvious in view of the referenced claims. The crystal forms (e.g. α -form crystal, β -form crystal, and crystal form) of (R)-2-(2-aminothiazol-4-yl)-4'[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide as recited in the reference claims are reasonably construed to be obvious variants of (R)-2-(2-aminothiazol-4-yl)-4'[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide in the absence of evidence to the contrary. As stated above, no patentable weight is being given to the "intended use" (i.e. overactive bladder, urinary incontinence, urinary urgency, and pollakiuria) of the instant claims as these claims are construed as directed to a composition; the reference claims are also reasonably construed as composition claims. To the extent that the instant composition recites (R)-2-(2-aminothiazol-4-yl)-4'[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide as the only active ingredient, someone of skill in the art at the time the instant invention was created would have deemed it obvious to create the instant invention with a reasonable expectation of success.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims of the copending applications have not in fact been patented.

Claim rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 USC 102(b) as being anticipated by Maruyama et al. (WO99/20607; equivalent English translation U.S. Patent 6,346,532 B1). Maruyama et al. teach the instant claimed composition comprising compound (R)-2-(2-aminothiazol-4-yl)-4'[2-(2-hydroxy-2phenylethyl)amino]ethyl]acetanilide (see claim 6 and Example 36). Applicant's statements of intended use (e.g. overactive bladder, urinary urgency, urinary incontinence, and pollakiuria) are not limited to the interpretation of composition claims. Thus, these claims are deemed to be anticipated by Maruyama et al. (WO99/20607).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

19 April 2007
CER

BRIAN-YONG S. KWON
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'B. Kwon', with a long horizontal flourish extending to the right.